IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KING DRUG COMPANY OF FLORENCE, INC. *et al.* Plaintiffs, v. CEPHALON INC., *et al*., Defendants.	:	CIVIL ACTION No. 06-1797-MSG

ORDER

AND NOW, this ____day of _____, 2009, upon consideration of Defendant Cephalon, Inc.'s Motion to Dismiss the Direct Purchasers' First Consolidated Amended Complaint and the Rite Aid Complaint and any response thereto, it is hereby ORDERED that the Motion is GRANTED and the First Consolidated Amended Complaint filed by Plaintiffs King Drug Company *et al*. and the Complaint filed by Plaintiffs Rite Aid Corp. *et al*., (Civil Action No. 09-3820), which has been consolidated with this action for all purposes, are DISMISSED WITH PREJUDICE.

BY THE COURT:

_____
Mitchell S. Goldberg, J.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KING DRUG COMPANY OF FLORENCE, INC. *et al.* Plaintiffs, v. CEPHALON INC., *et al*., Defendants..	:	CIVIL ACTION No. 06-1797-MSG

DEFENDANT CEPHALON, INC.'S MOTION TO DISMISS
THE DIRECT PURCHASERS' FIRST CONSOLIDATED AMENDED COMPLAINT
AND THE RITE AID COMPLAINT

Pursuant to F.R.Civ.P. 12(b)(6), Defendant Cephalon, Inc. hereby moves to dismiss the First Consolidated Amended Complaint filed by the Direct Purchaser Plaintiffs (Docket No. 193) and the Complaint filed by Plaintiffs Rite Aid Corp. *et al*., (Civil Action No. 09-3820), which has been consolidated with this action for all purposes (Docket No. 199). The grounds for this motion are set forth in the accompanying Memorandum.

Respectfully submitted,

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Dated: August 31, 2009

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KING DRUG COMPANY OF FLORENCE, INC. *et al.* Plaintiffs, v. CEPHALON, INC., *et al.* Defendants.	Civil Action No. 06-1797-MSG **ORAL ARGUMENT REQUESTED**

DEFENDANT CEPHALON, INC.'S COMBINED MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS THE DIRECT PURCHASERS' FIRST CONSOLIDATED AMENDED COMPLAINT AND THE RITE-AID COMPLAINT

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TABLE OF ABBREVIATIONS AND DEFINED TERMS

AC	First Consolidated Amended Class Action Complaint, Docket No. 193 (Aug. 10, 2009) ("King Drug Amended Complaint")
ANDA	Abbreviated New Drug Application
Cephalon	Defendant Cephalon, Inc.
Direct Purchaser Complaints	First Consolidated Amended Class Action Complaint, Docket No. 193 (Aug. 10, 2009) and Complaint And Demand For Jury Trial, Docket No. 199 (Aug. 21, 2009); C.A. No. 09-3820, Docket No. 1 (Aug. 20, 2009)
Direct Purchasers	Plaintiffs in Direct Purchaser Complaints
DOJ	U.S. Department of Justice
FDA	U.S. Food and Drug Administration
FTC	Plaintiff Federal Trade Commission
Generics	Defendants Barr Laboratories, Inc.; Mylan Laboratories, Inc.; Teva Pharmaceutical Industries, Ltd. together with its subsidiary Teva Pharmaceuticals USA, Inc.; and Ranbaxy Laboratories, Ltd., together with its subsidiary Ranbaxy Pharmaceuticals, Inc.
Hatch-Waxman	The Hatch-Waxman Act, Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (codified, in part, as amended at 21 U.S.C. § 355)
NDA	New Drug Application
PTO	U.S. Patent and Trademark Office
RAC	Complaint And Demand For Jury Trial, Docket No. 199 (Aug. 21, 2009); C.A. No. 09-3820, Docket No. 1 (Aug. 20, 2009) ("Rite-Aid Complaint")
Rite-Aid Plaintiffs	Plaintiffs Rite-Aid Corporation, Rite-Aid Hdqtrs. Corp., JCG (PJC) USA, LLC, Eckerd Corporation, Maxi Drug, Inc. d/b/a Brooks Pharmacy, and CVS Caremark Corporation
'516 Patent	U.S. Reissue Patent No. RE37,516

INTRODUCTION

This case is an effort to second-guess, under the guise of the antitrust laws, four separate agreements settling Hatch-Waxman patent infringement litigation between Cephalon and each of the four Generics over proposed generic versions of Cephalon's wakefulness drug, Provigil®. Following two-and-a-half years of vigorous litigation, each of the Generics separately agreed to drop its challenge to Cephalon's '516 patent in exchange for a license to launch its generic product in 2012, three years before that patent's exclusivity expired, subject to certain provisions allowing for even earlier entry (the "Provigil® Settlements" or "Settlements"). The parties also contemporaneously entered into other business transactions, including supply agreements, patent licenses and assignments, and product development collaborations.

Despite the obvious pro-competitive benefits and efficiencies the settlements achieved by resolving complex and costly litigation and securing early generic entry, Direct Purchasers – strangers to the underlying case – now challenge the agreements on behalf of a putative class of entities that purchase Provigil® directly from Cephalon. The gravamen of the Direct Purchaser Complaints is that payments made by Cephalon to the Generics in the contemporaneous transactions were actually disguised payments to secure the Generics' agreement to "delay" entry until 2012 (so-called "reverse payments"), and that the "strength" of Cephalon's claims under the '516 patent did not justify the agreed-upon entry date.

The Federal Circuit, whose precedent the Court should follow in order to ensure uniformity in the law of patent immunities (*see infra* at § I(B)), and other courts of appeals and district courts, uniformly have held that Hatch-Waxman settlements – even those with "reverse payments" – are lawful so long as the settlements do not restrict competition to any greater extent than the patent itself. These decisions expressly derive from Supreme Court precedent concerning the intersection of patent and antitrust law, and reflect two long-standing and

important public policies: first, the duty of courts to promote litigation settlements and thereby achieve efficiencies; and second, encouraging companies to innovate and develop new products by preserving a patentee's basic right to block infringing products during the life of its patent. The decisions also recognize that "reverse payments" do not reflect anticompetitive purpose, but rather are a natural consequence of the risks and incentives created by Hatch-Waxman itself. *See infra* at § I(D)(1).

The three principal theories of liability advanced by the Direct Purchaser Complaints – (1) that the contemporaneous business agreements entered into by the settling parties and others were actually "reverse payments," intended to induce the Generics to agree not to enter until 2012, *e.g.*, AC ¶ 5[1]; (2) that Cephalon's patent claims were "weak" and it likely would have lost the underlying litigation, *e.g.*, AC ¶¶ 6-7; and (3) that Cephalon and the Generics subjectively believed Cephalon was unlikely to prevail, *e.g.*, AC ¶ 6 – have been repeatedly rejected by the courts. In addition, the Rite-Aid Plaintiffs' claim that the Generics agreed to refrain from selling products in addition to those specifically at issue in the patent litigation is nothing more than a misguided effort to plead around the scope of the patent test, which necessarily upholds settlements to the full limit of the patent's claims. *See infra* § I.

The various arguments that have been made against the "scope of the patent" test, including by Direct Purchasers in prior briefing in this case, are unavailing. *First*, there is no split among the federal circuits on the appropriate treatment for Hatch-Waxman settlements, and the other cases cited to suggest a different standard are easily distinguishable. *See infra* § II. *Second*, even aside from the lack of judicial support, none of the various (and inconsistent)

[1] With a few exceptions discussed herein, the Rite-Aid Complaint is substantially identical to the King Drug Class Complaint. For simplicity, all complaint citations ("AC") are to the King Drug Amended Complaint, except where we specifically reference additional allegations in the Rite-Aid Complaint ("RAC").

alternative tests proposed to evaluate Hatch-Waxman settlements is analytically sound or workable. *See infra* § III. *Finally*, none of the litany of policy attacks on the prevailing standard comes close to undermining its rationale. *See infra* § IV.

Direct Purchasers also lack standing under established precedent to assert any antitrust challenge to the Provigil® Settlements. Their theory of harm rests upon impermissible speculation that but for the Settlements Cephalon would have lost the patent litigation or that one or more of the Generics would have entered the market "at risk" while the litigation was still pending. *See infra* § V. Ultimately, Direct Purchasers advance no concrete basis for their claim that they have paid more for Provigil® than they would have had the '516 patent litigation not settled.

In short, Direct Purchasers' effort to second-guess the terms of the Provigil® Settlements under the antitrust laws does not survive under Fed. R. Civ. P. 12(b)(6). The Direct Purchaser Complaints should be dismissed with prejudice.

FACTUAL AND REGULATORY BACKGROUND

A. The Hatch Waxman Act

The Settlements resulted from, and must be viewed in light of, the particular legislative scheme embodied in the Hatch-Waxman Act. Hatch-Waxman provides incentives both for innovator companies to develop and market new and innovative drug treatments as well as, where consistent with innovator patent rights, for generic companies to introduce low cost versions of those branded drugs. *See Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988). Through Hatch-Waxman, Congress has attempted to balance these potentially conflicting goals. Among other things, it establishes different types of market exclusivities – *i.e.,* periods of time in which either innovators are free from generic competition or in which the first filer is free from competition from other generics. The Act also sets forth

procedures for securing early determination of whether generics infringe innovators' patent rights.

NDAs. FDA approval is required before any drug can be introduced, or delivered for introduction, in interstate commerce. 21 U.S.C. §§ 331(d), 355(a) (2000). The FDA will not approve a New Drug Application ("NDA") until the applicant demonstrates that the drug is safe and effective for its intended use(s). *Id*. at § 355(b)(1). Upon approval of an NDA, the NDA holder *must* identify to the FDA those patents covering the approved drug, which in turn lists them in a publication called *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." *Id.* at § 355(b)(1); 21 C.F.R. § 314.53(e)(2009).

ANDAs and Paragraph IV Certifications. In contrast to innovator manufacturers, generic manufacturers submit Abbreviated New Drug Applications ("ANDAs"). ANDAs need not independently demonstrate safety and efficacy, but rather must show that the proposed generic is "bioequivalent" to an approved branded drug. *See* 21 U.S.C. § 355(d), (j)(2)(A)(ii) & (iv). If the Orange Book lists patents covering the relevant branded drug, Hatch-Waxman establishes a mechanism for generics to challenge listed patents, and for patentees to enforce their patent rights, before product launch. *See* 35 U.S.C. § 271(e)(2) (2000). In particular, as part of the ANDA, a generic manufacturer wishing to challenge a patent must certify that each patent listed is either invalid or will not be infringed by the proposed generic (a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(III)-(IV).

A Paragraph III certification indicates that the generic does not seek FDA approval until the expiration of the patent. *Id.* at § 355(j)(2)(A)(vi)(III), (5)(B)(ii). A Paragraph IV certification (such as those the Generics filed as to Provigil®), on the other hand, contests the validity or applicability of the patent. *Id.* at § 355(j)(2)(A)(vii)(IV). A Paragraph IV

certification is itself an act of infringement, 35 U.S.C. § 271(e)(2), triggering the patent holder's right to enforce its patent immediately and enabling the generic applicant to challenge the patent without making potentially infringing sales that would expose it to damages. When making a Paragraph IV certification, the ANDA applicant must provide a "Paragraph IV notification" to the holders of each applicable patent, stating that an ANDA has been filed and setting forth a detailed statement of the basis for its claims of invalidity and/or noninfringement. *Id.* at § 355(j)(2)(B).

Litigation Stay. If the patent holder does not file an infringement suit within 45 days of receiving a Paragraph IV notification, the FDA may approve the ANDA once all the innovator drug's applicable FDA exclusivities (*e.g.*, New Chemical Entity and Orphan Drug exclusivities, *see infra* § B) have expired and the FDA determines that the proposed generic is bioequivalent to the approved innovator drug and is otherwise approvable. *Id.* § 355(j)(5)(B)(iii). If, however, the patent holder files suit to enforce the patent within 45 days of receiving a Paragraph IV notification, FDA approval for that ANDA is automatically stayed for a period of 30 months, with certain exceptions,[2] or until the court hearing the infringement case determines that the patent is invalid, not infringed, or unenforceable, whichever is earlier (a "Paragraph IV litigation stay"). *Id.* During this time, the FDA may grant "tentative approval" for the ANDA, meaning the application is otherwise acceptable, but may not grant "final approval" until the stay and all other applicable FDA exclusivities have expired. *Id.* at § 355(j)(5)(B)(iv)(II)(dd).

[2] Where, as here, the active ingredient in the drug is deemed by the FDA a "New Chemical Entity," *infra* § B, the litigation stay lasts until seven-and-one-half years from approval (or 30 months from the date of receipt of the Paragraph IV notification, essentially whichever is longer). 21 U.S.C. § 355(j)(5)(F)(ii). In addition, another six months is added in cases where the FDA grants "pediatric exclusivity," *infra* § B. 21 U.S.C. § 355a(c)(1)(A)(i)(I).

180-day Generic First-Filer Exclusivity. As an incentive for generic companies to mount patent challenges, the first ANDA holder to file a Paragraph IV certification is entitled to a 180-day generic exclusivity period, during which time the FDA will not approve any other ANDAs containing Paragraph IV certifications that list the same branded drug and patent. *Id.* § 355(j)(5)(B)(iv)(I). If multiple applicants submit ANDAs with Paragraph IV certifications on the same day and no applicant has submitted an ANDA with a Paragraph IV certification before that day, the FDA has treated each same day applicant as a "first filer." The 180-day exclusivity period does not begin to run until one of the first-filers markets the drug or until any generic applicant obtains a final, non-appealable judgment against the patent, whichever is sooner. *Id.* § 355(j)(5)(B)(iv)(I), 355(j)(5)(D); *see* FDA, "Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day," 68 Fed. Reg. 45,252, 45,255 (Aug. 1, 2003).

B. The '516 Patent & Initial Paragraph IV Filings

Cephalon is a pharmaceutical company based in Frazer, Pennsylvania. AC ¶ 20, Document No. 193 (Aug. 10, 2009). On December 24, 1998, the FDA first approved Cephalon's NDA for Provigil® as a safe and effective treatment for excessive daytime sleepiness associated with narcolepsy. *Id*. ¶¶ 1, 52, 54, 63. Cephalon began marketing Provigil® in the United States shortly after it obtained FDA approval. *Id.* ¶¶ 54, 63.

Cephalon is the owner by assignment of the '516 patent, which expires on October 6, 2014. *Id.* ¶¶ 62, 64, 113. Shortly after it issued, Cephalon identified the '516 patent to the FDA for listing in the Orange Book for Provigil®. *See id.* ¶¶ 39-40, 63-64. Because the FDA later granted Provigil® "pediatric exclusivity" (as a result of studies Cephalon conducted on the pediatric population) the term of the patent is extended six months (to April 6, 2015) for FDA purposes. *See id*. ¶ 130.

The FDA awarded Cephalon "Orphan Drug Exclusivity" for Provigil® because it is indicated for the treatment of a rare disease. *Id.* ¶ 55. That exclusivity – prohibiting the FDA from approving any generic applications – was initially set to expire in December 2005, but was extended an additional six months (to June 2006) by the pediatric exclusivity designation. *See* 21 U.S.C. § 355a(c)(2).

The FDA also recognized that modafinil, the active ingredient in Provigil®, was a "New Chemical Entity," AC ¶ 54, which, pursuant to Hatch-Waxman, meant no generic company could submit an ANDA until December 24, 2002, four years after Provigil®'s FDA approval, 21 U.S.C. § 355(j)(5)(F)(ii). On that day, each of the four Generics (but not Apotex) submitted its ANDA for generic modafinil with a Paragraph IV certification with respect to the '516 patent, and notice of each filing was timely served on Cephalon. AC ¶ 56.

C. The '516 Patent Litigation And The Provigil® Settlements

Cephalon filed patent infringement claims in the U.S. District Court for the District of New Jersey against each of the Generics, triggering a Paragraph IV litigation stay. *Id.* ¶ 71. By February 1, 2006, after two-and-a-half years of vigorous litigation, Cephalon had separately settled each of these patent infringement claims. *See id.* ¶¶ 108, 116, 120, 124.

In each of the Provigil® Settlements, Cephalon licensed the generic to begin marketing in 2012, three years before the earliest date the generic could have entered the market had Cephalon prevailed on its patent claims. *Id.* In addition, each settlement included a provision that if any generic company successfully challenges the '516 patent, the Generics are contractually free to enter the market immediately. *See id.*

Cephalon and the Generics also entered into several business transactions, including modafinil supply agreements, intellectual property licenses and assignments, and product co-development deals. *See, e.g., id.* ¶¶ 110, 118-119, 122, 125-127. The Amended Complaint

alleges that these separate agreements were "disguise[s]," intended to compensate the Generics for staying off the market. *Id.* ¶ 5. Cephalon vigorously maintains that such payments were legitimate business arrangements for which fair consideration was paid, but accepts the allegation (as it must) for the limited purpose of this motion. However, as explained herein, Direct Purchasers' characterization of the arrangements as "exclusion" payments, *see, e.g., id.* ¶¶ 5-6 – commonly referred to in the case law as "reverse payments" – does not support an antitrust claim.

ARGUMENT

Direct Purchasers' Complaints include eight counts alleging violation of the antitrust laws. Each is brought under the Sherman Act, 15 U.S.C. §§ 1 or 2 (2000), and each should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6). All but Count VI (claiming conspiracy among the Generics) are directed to Cephalon alone or Cephalon in combination with one or all Generics. Counts I through IV assert that each of the four Provigil® Settlements is an unlawful restraint of trade under § 1 of the Sherman Act. Count V is a §1 claim based on a vaguely defined conspiracy among all the Defendants collectively. Counts VII and VIII charge Cephalon with monopolization and conspiracy to monopolize under § 2 of the Sherman Act, respectively. All the counts are based on the same allegations that the Provigil® Settlements are unlawful because they include "reverse payments" and/or because the "strength" of Cephalon's patent claims did not justify the terms of the Settlements, including the agreed-upon early generic entry date.

As set forth below, these allegations do not state a claim under either § 1 or § 2 of the Sherman Act because (1) under the prevailing scope of the patent test, adopted by the Federal Circuit whose law should be applied here, as well as by the Second and Eleventh Circuits, the

agreements are lawful exercises of Cephalon's patent rights; and (2) the Direct Purchasers lack standing.

I. THE SETTLEMENTS ARE LAWFUL BECAUSE THEY ARE WITHIN THE EXCLUSIONARY SCOPE OF THE '516 PATENT

A. Every Court Of Appeals To Assess Hatch-Waxman Settlements Has Adopted The Scope Of The Patent Standard Based On Sound Considerations Including Promoting Innovation, Encouraging Settlements, And Declining To Engage In Second-Guessing

The Federal, Second, and Eleventh Circuits have held that so long as Hatch-Waxman settlements do not restrain competition to any greater extent than the scope of the underlying patents, they do not violate the antitrust laws, even if the settlements include so-called "reverse payments," AC ¶ 5.[3] *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) ("*Cipro*"), *cert. denied*, 2009 WL 1738658 (U.S. June 22, 2009) ("The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent."); *In re Tamoxifen Citrate Antitrust Litig*., 466 F.3d 187, 212 (2d Cir. 2006) ("*Tamoxifen*"), *amending* 429 F.3d 396 (2d Cir. 2005), *cert. denied*, 127 S. Ct. 3001 (2007) (upholding dismissal of private challenges to Hatch-Waxman settlement, and stating that "[w]e generally agree … that 'simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law,' unless the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection'"); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1064, 1076 (11th Cir. 2005) ("*Schering-Plough*"), *cert. denied*, 126 S. Ct. 2929 (2006) (reversing FTC decision that had invalidated Hatch-Waxman settlements including "reverse payments" because restrictions were "no more

[3] "Reverse payments" refer to payments from innovator companies to generics. Although Cephalon vigorously disputes that the Provigil® Settlements included "reverse payments," and maintains that the payments were fair consideration for other business transactions, it accepts Direct Purchasers' allegation (as it must) for purposes of this motion only.

broad than the patent's own exclusionary power"); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003) ("*Valley Drug*"), *cert. denied*, 543 U.S. 939 (2004) ("reverse payment" settlement subject to antitrust scrutiny only if "found to have effects beyond the exclusionary effects of [defendant's] patent"). Importantly, the scope of the patent test applies equally to settlements of cases involving defenses of invalidity, non-infringement, or both. *See Schering-Plough*, 402 F.3d at 1075-76 ("An exception [to the "scope of the patent" standard] cannot lie, as the [FTC] might think, when the issue turns on validity (*Valley Drug*) as opposed to infringement (the Schering agreements).").

Under this standard, restrictions on the sale of generic products in Hatch-Waxman settlements (whether or not those settlements involve "reverse payments," which Cephalon disputes here) are within the "scope of the patent" unless they: (1) delay entry of generic products beyond the patent's expiration date; or (2) restrict the sale of products that exceed the patent claims. *See, e.g., Cipro*, 544 F.3d at 1337 (holding district court correctly "equat[ed] the exclusionary power of the patent with the scope of the patent claims without consideration of the uncertainty of patent validity"); *Valley Drug*, 344 F.3d at 1305, 1310 (so long as there is a "genuine dispute[]" over the patent claims, a settlement is lawful if within the exclusionary "potential" of the patent); *Schering-Plough*, 402 F.3d at 1076 (applying *Valley Drug* in case involving disputed infringement); *Tamoxifen*, 466 F.3d at 213 (holding that agreement "did not extend the patent monopoly by restraining the introduction or marketing of unrelated or non-infringing products"). No court of appeals has held to the contrary. *See infra* § II.

The prevailing scope of the patent standard recognizes that Hatch-Waxman settlements, because they involve patents rights, cannot be analyzed under the antitrust laws as simple horizontal restraints of trade, *i.e.*, agreements among competitors to limit competition. As the

Federal Circuit explained in *Cipro*, "a patent by its very nature is anticompetitive." 544 F.3d at 1333. To incentivize innovation, patents grant "the right to exclude" competitors from practicing the claimed invention. *Id*. (internal quotation marks omitted). Thus, while the antitrust laws generally prohibit anticompetitive conduct, "a patent is an exception to the general rule against monopolies and to the right of access to a free and open market." *Id.* (internal quotation marks omitted). The scope of the patent test thus emerged as a balance between the patent laws' goal of fostering innovation and antitrust laws' goal of prohibiting unreasonable restraints of trade. *See Cipro*, 544 F.3d at 1333 ("The district court appreciated this underlying tension between the antitrust laws and the patent laws. ... [T]he essence of the Agreements was to exclude the defendants from profiting from the patented invention. This is well within Bayer's rights as the patentee."); *Tamoxifen*, 466 F.3d at 202 ("It is the tension between restraints on anti-competitive behavior imposed by the Sherman Act and grants of patent monopolies under the patent laws, as complicated by the Hatch-Waxman Act, that underlies this appeal."); *Valley Drug*, 344 F.3d at 1307 ("A suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system is required…").[4]

The scope of the patent test also reflects the need to balance competitive concerns with the long-standing judicial policy of encouraging litigation settlements, which provide important public and private efficiencies. *See Tamoxifen*, 466 F.3d at 202 (stating that courts "are bound to

[4] Accordingly, contrary to the Direct Purchasers' position, decisions applying basic antitrust principles to agreements not to compete outside the patent context are inapposite, *e.g.*, *United States v. Topco Associates*, 405 U.S. 596 (1972) (illegal territorial market allocation among regional supermarkets), and *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990) (illegal territorial market allocation agreement among providers of bar review courses). *See, e.g.,* Status Conference Mem. of Pls. SAJ Distributors, Inc. & Stephen L. LaFrance Holdings, Inc., Docket No. 106 ("SAJ Status Report"), at 2 (June 19, 2009) (relying on *Topco* and *Palmer*). As the Eleventh Circuit in *Valley Drug* stated: "If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's order [finding the settlement agreements were unlawful market allocations]. This is not such a case, however, because one of the parties owned a patent." 344 F.3d at 1304.

encourage" the settlement of litigation) (internal quotation marks omitted); *Schering-Plough*, 402 F.3d at 1072 (noting policy favoring settlement and noting that "[p]atent owners should not be in a worse position, by virtue of the patent right, to negotiate and settle surrounding lawsuits"); *Cipro*, 544 F.3d at 1333 ("[T]here is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation."); *see generally Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1369 (Fed. Cir. 2001) ("[W]hile the federal patent laws favor full and free competition ... settlement of litigation is more strongly favored by the law."); *D.R. by M.R. v. East Brunswick Bd. of Educ.*, 109 F.3d 896, 901 (3d Cir. 1997) ("Settlement agreements are encouraged as a matter of public policy because they promote the amicable resolution of disputes and lighten the increasing load of litigation faced by courts.").

Settlements play a particularly important role in the patent context because they foster innovation by enabling patentees to achieve certainty in their patent rights. As the Eleventh Circuit explained: "[T]he caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product." *Schering-Plough*, 402 F.3d at 1075; *see also Valley Drug*, 344 F.3d at 1308 ("By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation."). Thus, where there are "legitimately conflicting [patent] claims, … a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act." *See Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931).

Finally, as explained in more detail *infra* at § I(D)(1), the scope of the patent test recognizes that settlement payments by branded companies to generics do not reflect anticompetitive purpose but are a natural consequences of the risks and rewards created by the

Hatch-Waxman Act itself. *See*, *e.g., Cipro*, 544 F.3d at 1333 n.11 ("[A] sizable exclusion payment from the patent holder to the generic manufacturer is not unexpected under the Hatch-Waxman Act, where the relative risks of litigation are redistributed".).

B. This Court Should Apply *Cipro* To Ensure Uniformity in the Law Of Patent Immunity

This Court should apply the Federal Circuit's *Cipro* decision in order to ensure a uniform body of law concerning patent immunities. The Federal Circuit has stated that "whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law." *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998). Direct Purchasers clearly challenge Cephalon's conduct in enforcing its patent (through settlement), and the scope of the patent standard clearly establishes a patent immunity from the antitrust laws. *Cipro*, 544 F.3d at 1336 (scope of patent test flows from analysis of "right to exclude afforded by the patent" and recognition that "patent is an exception to the general rule against monopolies"); *Valley Drug*, 344 F.3d at 1308 (preserving "patent immunity" for "enforcing the exclusionary right through settlement"). And in *Unitherm*, the Federal Circuit stated that even in cases that would be appealed to regional circuits, those courts should "apply Federal Circuit law or risk disturbing 'Congress's goal of ensuring patent-law uniformity' by applying its own law." *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1355 n.3 (Fed. Cir. 2004) (internal citation omitted), *rev'd on other grounds*, 546 U.S. 394 (2006); *see also Schinzing v. Mid-States Stainless, Inc.*, 415 F.3d 807, 811 (8th Cir. 2005) ("In examining this case, we adopt the Federal Circuit's precedent on substantive issues of patent law."); *In re Wellbutrin SR Antitrust Litig.*, Civ. A. Nos. 04-5525, 04-5878, 05-396, 2006 WL 616292, at *11 (E.D. Pa. Mar. 9, 2006) (holding that "the controlling authority [as to sham litigation issue] is the Federal Circuit, whose

decisions govern 'all antitrust claims premised on the bringing of a patent infringement suit'") (quoting *Nobelpharma*, 141 F.3d at 1069).[5]

C. The Prevailing Standard Is Derived From Supreme Court Precedent

The courts applying the scope of the patent standard expressly relied on Supreme Court precedent concerning the intersection of antitrust and patent law. In particular, the courts drew on *Walker Process Equipment, Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965), in which the Supreme Court considered the extent to which a patentee should be held liable under the Sherman Act for attempting to enforce patents against competitors. The Court made the critical distinction between patents *fraudulently* procured (enforcement of which could trigger antitrust liability) and patents that are merely found invalid (enforcement of which before the finding of invalidity does not give rise to antitrust liability). *Id.* at 177.

Like the prevailing Hatch-Waxman settlement standard, the *Walker Process* holding reflects a balance of the competing interests of patent and antitrust law. *See* 382 U.S. at 179-80 (Harlan, J., concurring) ("It is well also to recognize the rationale underlying this decision, aimed of course at achieving a suitable *accommodation in this area between the differing policies of the*

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[5] The Federal Circuit has now made clear that cases such as that at bar involve fundamental issues of patent immunity, *Cipro*, 544 F.3d at 1336. Because the Federal Circuit has exclusive jurisdiction over claims that "arise under" the patent laws, it will likely have jurisdiction over any appeal of this matter. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807-08 (1988) (jurisdictional test is whether plaintiffs' "right to relief necessarily depends on resolution of a substantial question of federal patent law"). This jurisdictional assessment is made based on the face of the complaint. *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 833 (2002). Here, Direct Purchasers' theory of liability depends on allegations that Cephalon has forfeited its patent immunity because the Settlements exceeded the scope of the '516 patent. *See* AC ¶¶ 5, 83, 87, 88, 100, 147. The Amended Complaints therefore necessarily raise issues of patent law. *See Unitherm*, 375 F.3d at 1357 ("[T]he determination of which actions can cause a patentee ... to lose the general protection of patent law ... is clearly an issue unique to patent law - and therefore inappropriate for ... the regional circuits"); *Cipro*, 544 F.3d at 1335-36 (settlement was "within the exclusionary zone of the patent and therefore protected by patent law"). Moreover, Direct Purchasers' theory of injury in fact – an essential element in any private antitrust claim, *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) – depends on showing that Cephalon would have lost the patent litigation had it not settled. Otherwise there is no "delay" in generic entry affecting prices and causing them injury. *See infra* at § V.

patent and antitrust laws.") *Id.* at 179. (emphasis added). As Justice Harlan explained in his concurrence, subjecting a patentee to antitrust liability merely because a patent might be "voidable … might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits." *Id.* at 180.

Thus, the Federal Circuit in *Cipro* cited *Walker Process* in concluding that the scope of the patent standard was "completely consistent" with Supreme Court precedent concerning the intersection of antitrust and patent law. 544 F.3d at 1323. The Eleventh Circuit in *Valley Drug* similarly observed that "Justice Harlan's concurrence [in *Walker Process*] explained that the effect of antitrust liability on the incentives for innovation and disclosure created by the patent regime must be taken into account when a court considers whether a patentee is stripped of its immunity from antitrust laws. … Employing this approach, we conclude that exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives." *Valley Drug*, 344 F.3d at 1307-08.[6]

Finally, courts adopting the scope of the patent standard *explicitly relied upon* several of the same Supreme Court cases erroneously claimed by the Direct Purchasers in prior briefing to be in conflict with the standard. *See Tamoxifen*, 466 F.3d at 202 (*citing United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963), for the proposition that patent exemption to antitrust laws does not extend "*beyond the limits of the patent monopoly*") (emphasis added)); *Schering-Plough*, 402

[6] The scope of the patent test is also consistent with decisions by district courts within the Third Circuit analyzing the intersection between patent and antitrust law. *See, e.g., Sheet Metal Duct, Inc. v. Lindab, Inc.*, No. 99-6299, 2000 WL 987865, at **2-3 (E.D. Pa. July 18, 2000) ("[A]ny allegations of antitrust resulting from a patent must extend beyond the rights granted in the patent…." (citations omitted)); *United States v. CIBA GEIGY Corp.*, 508 F. Supp. 1118, 1150 (D.N.J. 1976) ("[W]here a patentee exercises his patent in an effort to expand his monopoly beyond that reasonably implicit in the patent grant, he may collide with the antitrust laws." (citing *Standard Sanitary Mfg. Co. v. United States*, 226 U.S. 20, 28 (1912)).

F.3d at 1067 (same); *Valley Drug*, 344 F.3d at 1312 (*citing United States v. Masonite Corp.*, 316 U.S. 265 (1942), for proposition that "the patent exception to antitrust liability . . . is limited by the terms of the patent and the statutory rights granted the patentee."); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 248 (E.D.N.Y. 2003) (citing *Singer* for proposition that "a patent holder does not run afoul of the Sherman Act *unless the patent holder acts beyond the confines of the patent monopoly*") (emphasis added).[7]

D. The Allegations In The Direct Purchaser Complaints Do Not State A Claim Under The Prevailing Scope Of The Patent Standard

An application of the prevailing standard described above compels rejection of Direct Purchasers' attempt to substitute their own judgment for that of the settling parties, and to foist on the Court a regime where exposure to costly antitrust litigation and potential treble damage liability is the price to be paid for electing not to litigate patent cases to judgment. In particular, Direct Purchasers have not pled any facts suggesting the Provigil® Settlements cover products or time periods beyond the claims of the '516 Patent. Instead, Direct Purchasers assert that the settlements are unlawful for three reasons: (a) the settlements included payments from Cephalon to each of the Generic Defendants, *see* AC ¶¶ 5, 108, 112, 118, 122, 125-27; (b) Cephalon's patent claims were "weak" and Cephalon "likely" would not have prevailed or been able to obtain a preliminary injunction blocking "at risk" entry, *id.* ¶¶ 6-7, 83-84; and (c) the parties

[7] In prior briefing in this case, the Direct Purchasers argued that the scope of the patent test was inconsistent with the Supreme Court's decision in *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006) (applying four-part general permanent injunction standard to patent cases). They contended that because even a successful patentee is not automatically entitled to an injunction excluding competition, it somehow follows that a patentee that has not established its patent claims should not be allowed to exclude competition through settlement. But the argument compares apples to oranges. *eBay* is not an antitrust case or a Hatch-Waxman case, and the general standard for obtaining a permanent injunction has no logical connection to the standard applicable to whether Hatch-Waxman settlements violate the antitrust laws. Indeed, there is no reason to believe the parties in *eBay* could not lawfully have settled their claims. *See Standard Oil*, 283 U.S. at 171 (settlement of "legitimately conflicting [patent] claims . . . not precluded by the [Sherman] Act.").

believed that Cephalon's patent infringement claims were "weak," *Id*. ¶¶ 91-95. Each of these theories of liability has been repeatedly rejected. In addition, the Rite-Aid Plaintiffs' attempt unsuccessfully to avoid the scope of the patent test by alleging that the Settlements restricted the sale of actual or potential generic products other than the specific generic products at issue in the underlying litigation. RAC ¶¶ 52, 96, 104, 108, 111. These superficial allegations fail to allege that the Settlements were outside the exclusionary potential of the '516 patent, which extends to the full breadth of the patent's claims.

1. *The Federal Circuit And Other Circuits Have Recognized That "Reverse Payments" Are Not Anticompetitive, But A Natural Consequence Of The Hatch-Waxman Act*

As to Direct Purchasers' first theory, the Federal Circuit, as well as the Second and Eleventh Circuits, have conclusively rejected the position that the presence of payments from the patent holder to the patent challenger renders Hatch-Waxman settlements unlawful. The courts that have considered "reverse payments" have observed that any "suspicion" about payments to generics "abates upon reflection" because those payments are merely a by-product of the incentives and risks created by Hatch-Waxman. *Tamoxifen*, 466 F.3d at 208; *Cipro*, 544 F.3d at 1333 n.11. Therefore, even assuming the contemporaneous business transactions entered into by the Cephalon and the Generics somehow involved "reverse payments" and not, as Cephalon maintains, fair value consideration, they do not give rise to antitrust liability.

Patent litigation typically involves circumstances where the potentially infringing product already has been sold, and the potential infringer therefore risks both substantial damages (indeed, treble damages) as well as significant lost investment if found liable. *Cipro,* 261 F. Supp. 2d at 251. The potential infringer may mitigate that risk either by paying the patentee some amount of the profits earned or by agreeing to pay for a patent license. Conversely, the patentee may mitigate its risk of losing patent protection by accepting damages that are less than

its actual lost profits, or granting a license for a fee less than it would have accepted had its patent protection not been in jeopardy. Thus, in non-Hatch-Waxman patent settlements, payments generally flow from the defendant to the plaintiff (although, as explained above, consideration also flows to the settling infringer).

When innovator drug companies sue generics under Hatch-Waxman, everything is different. The mere filing of a Paragraph IV certification is itself an act of infringement, 35 U.S.C. § 271(e)(2), and generic companies thus are able to challenge patents without marketing a drug and subjecting themselves to the risk of having to pay damages for marketing an infringing product. *See Cipro*, 261 F. Supp. 2d at 252 ("[B]ecause of the generic manufacturer's entitlement under the Hatch-Waxman Amendments to institute patent litigation merely by filing [a Paragraph IV certification], the statutory scheme has the unintended consequence of altering the litigation risks of patent lawsuits."). Moreover, because a generic need not independently demonstrate the safety and efficacy of the drug through expensive clinical trials (as the NDA holder did), 21 U.S.C. § 355(j)(2)(A)(iv), the generic may have a relatively insubstantial investment at risk. On the other hand, the patentee faces the same type of risk it would face in the non-Hatch-Waxman context – potential loss of patent protection and loss of future profits, as well as substantial investment to obtain approval of an NDA – but does not have the upside of a potential damages award against the generic for selling an infringing product to use as negotiation leverage. *See Valley Drug*, 344 F.3d at 1309 ("Appellees have not explained why a monetary payment as part of a patent litigation settlement should be flatly prohibited as a *per se* violation, particularly where the alleged infringer has not yet caused the patentee any harm and the patentee does not have a damages claim to bargain with."). Indeed, as a result of state generic drug substitution laws, which in many cases require pharmacies to fill prescriptions with

the generic drug, the risk to a patentee in the Hatch-Waxman context is even greater (loss of most sales) than in other contexts (facing ordinary competition). *See* AC ¶ 47; *see also Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 609 F. Supp. 2d 786, 811 n.23 (S.D. Ind. 2009) (providing examples of steep erosion of brand sales upon generic entry, *e.g.,* loss of approximately 80% of sales within three weeks).

Thus, even though Cephalon vigorously maintains that its payments to the Generics were fair consideration for other business transactions, the courts applying the scope of the patent test have properly refused to condemn any settlement on the basis that it contained a "reverse payment." The Federal Circuit held that such payments are "particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them." *Tamoxifen*, 466 F.3d at 206; *Cipro*, 544 F.3d at 1333 n.11 ("[A] sizable exclusion payment from the patent holder to the generic manufacturer is not unexpected under the Hatch-Waxman Act, where the relative risks of litigation are redistributed."). The Second Circuit held that in light of settlement dynamics, there is "no sound basis for categorically condemning reverse payments employed to lift the uncertainty surrounding the validity and scope of the holder's patent." *Tamoxifen*, 466 F.3d at 207; *see also Cipro*, 261 F. Supp. 2d at 252 ("Accordingly, so-called reverse payments are a natural by-product of the Hatch-Waxman process. …"). The Eleventh Circuit observed that Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude." *Schering-Plough*, 402 F.3d at 1074. Finally, Judge Posner of the Seventh Circuit, sitting by designation, recognized that (1) it is dubious to consider "reverse payment" settlements anticompetitive, because the patentee might have won the suit, thereby completely excluding competition, and (2) a ban on "reverse-payment settlements would reduce the incentive to

challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive." *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation).

2. *The Federal Circuit And Other Circuits Have Refused To Base Antitrust Liability On* Ex Post *Assessments Of Patent Merits*

Next, in an effort to twist the plain meaning of the decisions holding that settlements within the scope of the patent are lawful, Direct Purchasers contend that the Provigil® Settlements exceed the scope of the '516 Patent because Cephalon "likely" would have lost the patent suit, Cephalon was "unlikely" to have blocked at-risk entry with a preliminary injunction and, the patent claims were otherwise too "weak" to justify the agreed-upon market entry date of 2012. AC ¶¶ 6-7, 83-84.

These allegations do not state a claim because the scope of the patent test focuses on time periods and products covered, not the *merits* of the disputed claims. Indeed, the courts of appeals adopting the prevailing scope of the patent standard specifically have refused to make the validity of Hatch-Waxman settlement agreements turn on an *ex post* inquiry into the merits of patent claims. *See Cipro*, 544 F.3d at 1336 ("[T]he court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment."); *Tamoxifen*, 466 F.3d at 203 ("We cannot judge this … settlement on the basis of the likelihood *vel non* of … success had [the matter] not settled. ..."); *Valley Drug*, 344 F.3d at 1308 (holding that even a subsequent judicial determination of invalidity of the patent at issue did not render a Hatch-Waxman settlement unlawful).

This refusal to second-guess patent settlements is well founded. Litigation outcomes are inherently uncertain, which is why parties settle and courts encourage settlements. Exactly the opposite result – deterring settlements – would result if antitrust liability in a collateral attack by

a stranger to the underlying case depended on a later court's after-the-fact assessment of the merits of the patent claims and defenses. *Id.* at 1308 ("Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent."); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 529-30 (E.D.N.Y. 2005) ("[M]aking the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court's assessment of the patent's validity might chill patent settlements altogether."); *see also Christiansburg Garment Co. v. EEOC*, 434 U.S. 412, 422 (1978) ("[N]o matter how meritorious one's claim may appear at the outset, the course of litigation is rarely predictable.").

3. *Whether A Party Believes Its Patent Claims Or Defenses Are Strong Or Weak Has No Bearing On Its Right To Settle The Claims*

Direct Purchasers also posit that the Provigil® Settlements were illegal because the parties allegedly believed Cephalon's patent claims were "weak." *See*, *e.g.*, AC ¶ 6. Once again, this theory of liability has been properly rejected by courts holding that the "private thoughts" of litigants concerning the strength or weakness of the patent claims are irrelevant to the legality of Hatch-Waxman settlements. *See Tamoxifen*, 466 F.3d at 210 ("[W]e doubt the wisdom of deeming a patent effectively invalid on the basis of a patent holder's fear of losing it."); *Asahi Glass*, 289 F. Supp. 2d at 992-93 ("[T]he private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case."). As Judge Posner held in *Asahi Glass*:

> It is not "bad faith" . . . to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights. No one can be *certain* that he will prevail in a patent suit.

289 F. Supp. 2d at 993. Moreover, the type of unreliable, inconclusive factual allegations Direct Purchasers assert in support of their contention that Cephalon doubted the "strength" of its claims – *e.g.*, contingency business planning for generic competition, AC ¶ 94, warnings to market analysts, *id.* ¶ 95 – demonstrate the practical difficulties in analyzing a parties' contemporaneous views of the case. As discussed further below, *see infra* § III, the Direct Purchaser Complaints confuse (and, more importantly, jurors may confuse as well) conservative business management (planning for the possibility of generic competition) with a company's genuine belief in the strength of its case. The best evidence demonstrating the latter, however, is most likely privileged communications with counsel. Thus, the prospect of having to waive privilege to defend a settlement, or alternatively having to risk treble damages to preserve the privilege, could both chill settlements and inhibit full and frank communications with counsel.

4. *The Provigil® Settlements Do Not Include Products Outside The '516 Patent's Exclusionary Scope*

The Rite-Aid Plaintiffs' attempt to avoid dismissal under the prevailing standard by alleging that while the Generics agreed not to sell any generic version of Provigil® before 2012, the "'516 Patent could not be used to block all generic versions of Provigil®." RAC ¶ 52. Contrary to the Rite-Aid Plaintiffs' allegation, the patent litigation *did* have the potential to restrict the Generics from selling not only the particular ANDA modafinil composition at issue, but also any generic product covered by Cephalon's construction of the '516 patent claims. *See Pfaff v. Wells Elecs., Inc.*, 5 F.3d 514, 518 (Fed. Cir. 1993) (prior court's interpretation of patent claims, if necessary to infringement finding, has preclusive effect in subsequent litigation between same parties); *Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1323 (Fed. Cir. 1987) (same); *Roche Palo Alto LLC v. Apotex, Inc.*, 526 F. Supp. 2d 985, 991 (N.D.

Cal. 2007) (where generic company filed new ANDA after losing prior ANDA litigation, "issue preclusion would prevent [generic] from relitigating these claim construction issues").

Moreover, as the name suggests, the relevant issue under the "scope of the patent" test is the exclusionary potential of the patent, not the scope of the *lawsuit.* It is axiomatic that Cephalon has a right to exclude competition to the full breadth of the '516 patent's claims. *See, e.g., Cipro*, 544 F.3d at 1337 (district court correctly "equat[ed] the exclusionary power of the patent with the scope of the patent claims"); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) ("It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'").

Under the scope of the patent test, then, a settlement is a lawful exercise of patent rights if it includes *any* generic products within Cephalon's good faith construction of the '516 patent claims, not just those products being litigated at the time. Any other result would invite the same *ex post* inquiry that the scope of the patent test eschews, because there is no difference between analyzing later whether the particular generic drug at issue infringed and whether additional generic compositions infringed. *See Valley Drug*, 344 F.3d at 1305, 1310 (declining to review merits of patent case so long as there was "genuine dispute"); and *Schering-Plough*, 402 F.3d at 1075-76 ("An exception [to the scope of the patent standard] cannot lie, as the Commission might think, when the issue turns on validity (*Valley Drug*) as opposed to infringement (the Schering agreements."). Tellingly, the Rite-Aid Complaint does not challenge the *bona fides* of Cephalon's claim construction. And while it alleges that two of the Settlements preclude the sale of "generic equivalents of successor products" of Provigil®, RAC ¶¶ 96, 108, it includes no allegations plausibly explaining why these restrictions would fall outside the exclusionary scope

of the '516 patent. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2006) (a complaint must state a plausible claim grounded in factual allegations to survive a motion to dismiss).

Permitting settlements to the full extent of good faith patent claim construction is also practical, and consistent with the duty of courts to promote settlements. Like many composition patents, the '516 patent covers a range of possible compositions of the drug.[8] If settlements were limited only to the specific composition submitted under a generic's ANDA, the generic potentially could modify that composition, submit a new ANDA, file a new Paragraph IV letter, and begin the litigation all over again. The patent holder wishing to settle an infringement suit would therefore face the Hobson's choice of (1) entering into a settlement covering only the current, specific ANDA pharmaceutical composition, leaving open the possibility of future infringement litigation over other ANDAs for the same drug, or (2) not settling at all. Adopting the Rite-Aid Plaintiffs' position would compromise the very certainty that settlements are designed to provide, needlessly wasting judicial resources, and chilling settlements in contravention of the duty of courts to promote them. *See Tamoxifen*, 466 F.3d at 202.

Accordingly, the Settlements here included only products within the exclusionary power of the '516 patent, and the Direct Purchaser Complaints therefore should be dismissed.

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[8] Among other things, the '516 patent claims: "[a] pharmaceutical composition comprising a substantially homogeneous mixture of modafinil particles, wherein at least about 95% of the cumulative total of modafinil particles in said composition have a diameter of less than about 200 microns"; and also "[a] pharmaceutical composition in an oral dose form comprising: an amount of modafinil effective to alter a somnolent state of a mammal upon oral administration, said amount of modafinil being in the form of solid modafinil particles, said particles have a size distribution wherein at least about 95% of the cumulative total of said particles have a diameter of less than about 200 microns." *See* U.S. Patent RE37,516 (claims 1 & 7), *available at* www.uspto.gov. *See Ieradi v. Mylan Labs., Inc*., 230 F.3d 594, 600 n.3 (3d Cir. 2000) (stating that courts may take judicial notice of facts that are "not subject to reasonable dispute [and are] capable of accurate and ready determination by resort to a source whose accuracy cannot be reasonably questioned"); *see also Messer v. HO Sports Co., Inc.*, Civ. A. No. 06-826, 2007 WL 3113334, at *6 (D. Or. Oct. 22, 2007) (taking judicial notice of substance of patent claims).

5. *Direct Purchasers' Allegations Concerning A Broad Conspiracy Among All Five Defendants Fail Under* Twombly *And* Monsanto

The conclusory assertion that there was a broad conspiracy among all defendants (Count V), as distinct from four separate Settlements (Counts I-IV), fails to state a claim. The Settlements were entered into months apart, AC ¶¶ 108, 116, 120, 124, and no facts are pleaded plausibly suggesting they were part of an overarching conspiracy, such as the time, place and manner of formation of any such conspiracy or facts excluding the possibility that the parties to each Settlement were acting in their independent economic self-interest. *See Twombly*, 550 U.S. at 566 (dismissing claim because plaintiff failed to allege facts justifying inference that defendants had not acted unilaterally out of self-interest); *see generally Monsanto Co. v. Spray-Rite Service Corp.*, 465 U.S. 752, 764 (1984) (holding that antitrust plaintiff "must [present] evidence that tends to exclude the possibility that the [alleged conspirators] were acting independently").

II. THERE IS NO SPLIT IN APPELLATE AUTHORITY ON REVERSE PAYMENTS

Direct Purchasers have claimed, erroneously, that there is disagreement among the federal courts, including the courts of appeals, on the appropriate standard for Hatch-Waxman settlements. In particular, they assert: (1) that the Sixth Circuit and the District of Columbia support their view that "reverse payment" settlements constitute "illegal market allocations;" (2) that the Eleventh Circuit scope of the patent standard is "significantly different" from the Federal and Second Circuits'; and (3) that the District of New Jersey's decision in the *K-Dur* litigation provides support for their position. *See, e.g.,* SAJ Status Report at 2-3. Direct Purchasers'

arguments cannot withstand scrutiny. The Federal Circuit and other courts have repeatedly rejected the same efforts to manufacture some split in authority.[9]

A. The Sixth Circuit *Cardizem* Decision And The District Of Columbia Circuit's *Andrx* Decision Are Inapposite

Direct Purchasers seek to create the illusion of a circuit split principally by citing the Sixth Circuit's decision in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) ("*Cardizem*"), and the District of Columbia's decision in *Andrx Pharmaceuticals, Inc. v. Biovail Corp. Int'l.*, 256 F.3d 799 (D.C. Cir. 2001) ("*Andrx*"). Neither case is on point, though, because neither involves a Hatch-Waxman settlement.[10] Both cases involve challenges to the same *interim* agreement in which a branded drug company paid a generic, *first*, not to launch its proposed generic or other non-infringing products until it obtained "a favorable, final and nonappealable" judgment; and, *second*, not to "relinquish or otherwise compromise" its 180-day generic exclusivity (thereby preventing other generics from entering). *See Cardizem*, 332 F.3d at 902-03 (internal quotation marks omitted).

Because the interim agreement did not achieve certainty in patent rights or resolve litigation, the courts – unlike the Federal Circuit and other authorities relied upon by Cephalon – had no reason to consider the appropriate standard for judging *settlements*. As the DOJ and FTC explained in a joint filing in *Cardizem*:

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[9] Indeed, the FTC's current Chairman has candidly acknowledged the FTC's strategy to attempt to *create* a circuit split in the hopes of persuading the Supreme Court to accept review. *See* Oral Statement of Commissioner Jon Leibowitz, Hearing of the Senate Judicial Committee (Jan. 17, 2007) at 3, *available at* http://www.ftc.gov/speeches/leibowitz/071701oralstatement.pdf (last accessed Aug. 29, 2009).

[10] *Andrx* is irrelevant for the further reason that it did not address whether the agreements violated the antitrust laws, but instead was focused on whether the plaintiff had sufficiently pleaded antitrust injury *assuming* there was a violation. 256 F.3d at 804, 812, 814. In their status conference report, Direct Purchasers incorrectly asserted that the District of Columbia Circuit *held* that "reverse payment" settlements could be viewed as market allocations. *See* Status Conference Mem. (Meijer, Inc., Meijer Distribution, Inc.), Docket No. 161 ("Meijer Status Report"), at 2 n.2 (June 19, 2009).

> The distinction [between interim agreement and settlements] is important because the calculus of competitive costs and benefits is substantially different. … While final settlements of infringement claims may have anticompetitive effects, they may facilitate innovation and investment in the patented technology by eliminating litigation risks and providing certainty over patent rights. The type of interim agreement at issue in [*Cardizem*], on the other hand, may have none of those effects, because it leaves questions of patent validity and infringement to be litigated.

U.S. Amicus Br. ("*Cardizem Amicus* Br."), *Andrx Pharmaceuticals, Inc. v. Kroger Co.,* 125 S. Ct. 307, No. 03-779, ("FTC *Cardizem Amicus*"), *available at* 2004 WL 1562075, at *17 (July 9, 2004) (internal quotation marks and citations omitted); *see also* Opinion of the Federal Trade Commission at 13 n.26, *In re Schering-Plough Corp.*, Docket No. 9297 (Dec. 9, 2003), *available at* www.ftc.gov/os/adjpro/d9297/031218commission.pdf (last accessed Aug. 3, 2009). ("[*Cardizem*] can be distinguished on its facts" from *Schering-Plough* because *Cardizem* involved only an interim agreement and, therefore, "it would be more difficult to claim that the agreement was ancillary to an efficient disposition of the litigation.").

Moreover, as the Federal Circuit in *Cipro* recognized, "the agreement [in *Cardizem*] clearly had anticompetitive effects outside the exclusionary zone of the patent." 544 F.3d at 1335 (noting that parties agreed to restrictions on sale of products acknowledged to be noninfringing and also agreed to block subsequent generics); *see also* FTC *Cardizem Amicus* Br. at *12 ("The better reading of the Sixth Circuit's opinion is that *it does not* deem illegal *per se* every settlement agreement that includes a reverse payment in exchange for the exclusion from the market of an allegedly infringing product.").

B. The Eleventh Circuit Scope Of The Patent Standard Is Consistent With The Federal And Second Circuits' Standard

Direct Purchasers also contend that, under Eleventh Circuit precedent, settlement restrictions are within the "scope of the patent" only if they pass a "fact-intensive inquiry" that

somehow measures the settlement terms against the merits of the patent case. *See* Report of Pl.'s King Drug Company of Florence, Inc. *et al.*, Docket No. 159 ("King Drug Status Report"), at 2 n.3 (June 19, 2009). This argument is based on a misinterpretation of the district court's decision on remand from *Valley Drug*, *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005), where the court invalidated a provision of a brand-generic agreement. *Id.* at 1301. Critically, *Terasozin* did not involve a Hatch-Waxman settlement, but rather an interim agreement in which the generic agreed not to market pending the branded company's appeal of a decision invalidating the patent at issue. *Id.* at 1294.[11] Thus, the case is distinguishable for the same reasons as *Cardizem* and *Andrx*.

The Eleventh Circuit itself in *Valley Drug* had stated that this unique appellate-stay provision warranted different treatment than a final settlement allowing for early entry. In particular, *Valley Drug* involved two separate agreements: (1) the Abbott-Zenith final settlement allowing for entry in advance of the patent's expiration; and (2) the Abbott-Geneva interim agreement including the appellate-stay provision. *Valley Drug*, 344 F.3d at 1300. In analyzing the *settlement*, the Eleventh Circuit noted that the agreement "appears to be no broader than the potential exclusionary effect of the '207 patent, and was actually narrower to the extent it permitted Zenith to market its drug before the '207 patent expired." *Id.* at 1305. Not only did the court not consider the patentee's likelihood of success had the matter not settled, but it expressly observed that such inquiry "would tend to discourage settlement of any validity challenges except those that the patentee is certain to win at trial and the infringer is certain to lose." *Id*. at 1308.

[11] Other provisions of the same agreement as well as a separate final settlement which were at issue in the Eleventh Circuit appeal in *Valley Drug* were no longer part of the case when the district court issued its remand decision. *Terazosin*, 352 F. Supp. 2d at 1294.

In stark contrast, the court framed the question for the *interim agreement* as whether the patent would "have allowed Abbott to obtain preliminary injunctive relief or a stay of an adverse judgment pending appeal," and remanded to the district court to make that determination. *Id.* at 1305 & n.17. This distinction makes good sense, because the Geneva interim agreement did not resolve litigation or achieve certainty with respect to patent rights. In effect, the parties had simply stipulated to a private injunction pending appeal with no pro-competitive benefit, and in that unique circumstance, the court looked to whether the already-invalidated patent could have secured that same exclusion.

The Eleventh Circuit in *Schering-Plough* subsequently distinguished *Terazosin* on the same basis, namely that it involved an interim agreement, not a settlement. *Schering-Plough*, 402 F.3d at 1065 n.14 ("We note that the case at bar is wholly different from [the *Valley Drug* remand decision]. The critical difference is that the agreements at issue in [*Terazosin*] did not involve final settlements of patent litigation, and, moreover, the [*Terazosin*] agreements did not permit the generic company to market its product before patent expiration. … Given these material distinctions, the same analysis cannot apply.").

Accordingly, because no appellate stay provision or interim agreement is before the Court, *Terazosin* is irrelevant.[12]

Two Eleventh Circuit cases since *Valley Drug* confirm that its standard (like the Federal and Second Circuits') measures a patent's exclusionary potential by the nominal scope of its claims, not by the patentee's likelihood of success on the merits. In addition to distinguishing interim agreements from settlements, the Eleventh Circuit held in *Schering-Plough* that a

[12] One court applying the scope of the patent test questioned whether *Terazosin* was correctly decided even in the limited context of an appellate-stay provision. *See Cipro*, 363 F. Supp. 2d at 526 ("It is not certain that the district court correctly interpreted the [*Valley Drug*] opinion…").

settlement "fell well within the protections of the '743 patent" by reference to the patent's claims and expiration date, without any analysis of the validity or infringement arguments raised by the generics. 402 F.3d at 1076. Likewise, in the Eleventh Circuit's most recent Hatch-Waxman settlement decision, *Andrx Pharms., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005), the court found that, based on its claims alone, the patent covered the generic product. *Id.* at 1235 ("With regard to the first element [i.e., the scope of the patent], the allegations in Andrx's complaint demonstrated that the '320 patent was necessary to the manufacture and sale of controlled release naproxen medication."). *Id.* As in *Schering-Plough*, the court did not discount or limit that scope based on an assessment of the patent merits – much less apply a preliminary injunction standard – even though the complaint alleged that the patent could not be "held to be valid upon adjudication" *Elan,* 421 F.3d at 1231-32.

C. A Special Master Recently Recommended Adoption Of The Prevailing Scope Of The Patent Standard In The *K-Dur* Case, Formerly The Only Federal Authority Against The Scope Of The Patent Standard

Direct Purchasers also rely on the district court decision in *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517 (D.N.J. 2004), a private suit arising from the settlements subsequently upheld in *Schering-Plough*, as supporting authority because the court there denied a motion to dismiss. *See* Meijer Status Report at 2 n.4. However, in finding that the complaint in alleged a settlement that "grant[ed] rights to [the innovator company] in excess of what is granted by the patent," the court specifically noted restrictions on non-infringing generic competitor drugs and bioequivalence research relating to the branded drug. *Id.* at 532.

Moreover, the opinion in *K-Dur* is of limited precedential value, principally because it was decided before the Federal Circuit's decision in *Cipro*, the Second Circuit's decision in *Tamoxifen*, and the Eleventh Circuit's decision in *Schering-Plough*. The court drew upon the precedent available at the time: *Cardizem* (which, as stated above, is distinguishable) and the

FTC's *Schering-Plough* decision and order (which the Eleventh Circuit later vacated because it was based on an "inflexible" legal theory that failed to account for the realities of Hatch-Waxman litigation, *see Schering-Plough*, 402 F.3d at 1075). *See K-Dur*, 338 F. Supp. 2d at 533 & n.21. Recently, recognizing that the *K-Dur* motion to dismiss decision "was issued … before the 11th Circuit's decision in *Schering[-Plough]* and before the decisions of the Second and Federal Circuits following the 11th Circuit approach," the special master in the case, Judge Orlofsky (former D.N.J. judge) recommended that the court adopt the prevailing scope of the patent standard for purposes of summary judgment. *In re K-Dur Antitrust Litig.*, Civ. A. No. 01-1652(JAG), 2009 WL 508869, at *26 (D.N.J. Feb. 6, 2009).[13]

III. THERE IS NO SOUND ALTERNATIVE TO THE PREVAILING SCOPE OF THE PATENT STANDARD

Parties opposing the "scope of the patent" test, including Direct Purchasers in prior briefing in this case, have presented a host of alternative and inconsistent standards, none of which is analytically grounded or practical. These alternative proposals fall broadly into three categories: (1) invalidating as *per se* unlawful[14] or presumptively unlawful[15] any settlement with a reverse payment; (2) conducting an *ex post* patent merits inquiry and invalidating a settlement if either the patentee could not have obtained a preliminary injunction[16] or if, after an objective review of the merits of the patent case, the settlement terms do not reasonably reflect the

[13] Plaintiffs' objections to Judge Orlofsky's recommendation are pending. *See HIP Health Plan of Fla., Inc. v. Schering-Plough, et al.*, C.A. No. 01-1652, Docket No. 737 (Mar. 20, 2009).

[14] This proposal applies the holding in *Cardizem* about interim agreements to final settlements. *See supra* at § II(A).

[15] This proposal applies the FTC standard expressly rejected by the Eleventh Circuit in *Schering-Plough*, 402 F.3d at 1074

[16] This approach applies to final settlements the holding in *Terazozin* concerning an interim appellate stay provision. *See supra* at § II(B).

"strength" of the patent;[17] and (3) invalidating a settlement if the terms do not reasonably reflect the parties' *subjective* "expectations" or "evaluations" of the patent merits.[18] None of these tests, however, affords a sound or workable alternative to the scope of the patent test.[19]

A. There Is No Viable Rationale For Condemning Reverse Payment Settlements

Any rule prohibiting "reverse payment" settlements or making them presumptively unlawful is untenable. These approaches are based on the assumption that all settlements can be structured by adjusting market entry date alone, which is simply not true. As explained above, generics have disproportionate leverage in Hatch-Waxman settlement negotiations because, inter alia, they can test the validity of a patent without risking damages for infringement. *See supra* § I(D)(1) (and cases cited). Because a generic may be willing to take a disproportionate chance in litigating a case to conclusion in view of its reward/risk ratio, there may be circumstances where a cash payment is necessary to achieve settlement. *Schering-Plough*, 402 F.3d at 1074 ("Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude."). As explained by one scholarly article:

> Over optimism, either by both parties or by the entrant alone, can produce a gap between the latest date at which the generic is willing to accept entry in order to settle litigation and the earliest

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[17] This approach applies the DOJ's now-abandoned position rejected by the Federal Circuit in *Cipro*, 544 F.3d at 1337.

[18] This approach applies the new standard proposed by the DOJ to the Second Circuit, Br. For U.S., *Arkansas Carpenters Health & Welfare Fund v. Bayer, AG*, No. 05-2815, 2852 (2d Cir. July 6, 2009), *available at* 2009 WL 2429249.

[19] Although some of these approaches have been advanced by the FTC and DOJ, neither agency's view is authoritative or entitled to deference. *Appalachian States Low-Level Radioactive Waste Comm'n v. Pena*, 126 F.3d 193, 198 (3d Cir. 1997) ("No deference is due an agency's litigation position"); *United States v. Trident Seafoods Corp.*, 60 F.3d 556, 559 (9th Cir. 1995) (same). The Sherman Act is a judicially-administered statute, *State Oil Co. v. Khan*, 522 U.S. 3, 20-21 (1997) (noting "the accepted view that Congress expected the courts to give shape to the [Sherman Act's] broad mandate by drawing on common-law tradition.") (internal quotation marks omitted), as demonstrated by the Federal Circuit's *Cipro* decision, where the court expressly considered and rejected the DOJ's views, 544 F.3d at 1334-35, 1337; and the Eleventh Circuit's *Schering-Plough* decision, when that court vacated an FTC ruling, 402 F.3d at 1074.

> date at which the innovator is willing to permit entry. A cash payment can bridge the gap.

Kent S. Bernard & Willard K. Tom, "Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles," 15 Fed. Cir. B.J. 617 (2006).

A rule that bans "reverse payments" altogether inevitably would render settlements unfeasible in some situations, in direct contravention of the strong public policy favoring settlement of litigation that animates the decisions upholding Hatch-Waxman settlements. *See, e.g.*, *Tamoxifen*, 466 F.3d at 202 ("[C]ourts are bound to encourage the settlement of litigation.") (internal quotation marks and citation omitted). It also would harm the public, because generics necessarily would have lost many of the cases that could have been settled on terms involving early market entry, resulting in exclusion of their generic drug for the remaining life of the patent. *See Schering-Plough*, 402 F.3d at 1074. In turn, deterring settlements can have a dampening effect on innovation itself, as the Second Circuit expressly recognized. *Tamoxifen*, 466 F.3d at 203 ("Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation.").

Condemning reverse payments because the parties hypothetically "could" have settled on an earlier entry date without payment also contravenes fundamental antitrust principles. The courts have declined to impose on private parties a duty to enter agreements on terms that are the *most* pro-competitive. In *Cipro*, 363 F. Supp. 2d at 532, the court observed that "Requiring parties to a lawsuit either to litigate or negotiate a settlement in the public interest, at the risk of treble damages is, as a practical matter, tantamount to establishing a rule requiring litigants 'to continue to litigate when they would prefer to settle' and 'to act as unwilling private attorneys general and to bear the various costs and risks of litigation.'" The court therefore found that

"Bayer and Barr cannot be penalized just because plaintiffs can imagine a more pro-competitive settlement, if the agreement they did reach does not adversely affect competition beyond the scope of the '444 Patent." *Id.* at 536; *see also Verizon Commc'n Inc. v. Law Offices of Curtis Trinko, LLP*, 540 U.S. 398, 415-16 (2004) (Sherman Act does not impose obligation on defendant to "alter its way of doing business whenever some other approach might yield greater competition"); *USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 512-13 (7th Cir. 1982) (Posner, J.) (antitrust laws do not create positive duty to enhance competition); *Am. Motor Inns, Inc., v. Holiday Inns, Inc.*, 521 F.2d 1230, 1249 (3d Cir. 1975) (requiring businesses to enter into most procompetitive agreements possible would improperly make businesspeople "guarantors that the imaginations of lawyers could not conjure up some method of achieving the business purpose in question that would result in a somewhat lesser restriction of trade.").

B. A Standard Based On *Ex Post* Merits Assessments Is Unworkable, Unreliable, And Likely To Chill Settlements

As the courts adopting the scope of the patent test have recognized, any standard premised on an *ex post* assessment of the patent merits also would be so unpredictable as to chill settlements, contrary to the courts' duty to promote them. *Supra* § I(D)(2); *see, e.g., Cipro*, 544 F.3d at 1337; *Tamoxifen*, 466 F.3d at 212 n.26. Moreover, *any* standard that depends on the amorphous concept of *ex post* evaluation of patent "strength" is not workable in practice. How, for example, should a judge or jury define a "strong" or a "weak" patent? Should the inquiry be purely qualitative, or should the fact-finder artificially quantify the likelihood that the patentee would have prevailed had the case been tried? Even if such an exercise were possible, does a 51 percent probability mean a patent is "strong" and a 49 percent probability mean a patent is "weak"? If not, should there be some other threshold below which a patent is too "weak" to support certain settlement terms? Should there be some amorphous sliding scale comparing the

"weakness" of a patent to the amount of consideration given to the generic? Proponents of the merits-based standards have not meaningfully addressed these questions.

Moreover, the efficacy of retrying the underlying patent case is highly doubtful. Even the FTC has "question[ed] the utility of a rule that would give decisive weight to an after-the-fact inquiry into the merits of the patent issues in a settled case." Opinion of the Commission, *In re Schering-Plough Corp.*, No. 9297 ("*FTC Schering-Plough*"), at 33, *available at* www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf (last accessed August 5, 2009). And the DOJ – which previously had advocated this approach – recently conceded it to be unworkable. *See* Br. for the U.S., *Arkansas Carpenters Health & Welfare Fund v. Bayer, AG*, No. 05-2851, 2852 (2d Cir. July 6, 2009), *available at* 2009 WL 2429249 ("DOJ *Cipro* Br."), at 25-26 ("[A] mini-trial of the patent issue … could reduce parties' incentives to settle … [and] would align the infringement defendant with the infringement plaintiff in the antitrust case, reducing the accuracy of any validity determination.").[20]

At bottom, none of these *ex post* inquiries are either feasible or appropriate, as courts applying the prevailing standard have explicitly recognized in eschewing ex *post* inquiry. If the parties themselves were unable to predict the outcome of the case because patent litigation is inherently uncertain, *Valley Drug*, 344 F.3d at 1308 ("Patent litigation is too complex and the results too uncertain for parties to accurately forecast" the outcome), a judge or jury cannot meaningfully do so retrospectively.

[20] There were two appeals from the Eastern District of New York's decision in *Cipro*. The appeal of the indirect purchasers case went to the Federal Circuit because it included state law claims expressly raising issues of patent law. *Cipro*, 544 F.3d at 1330. The appeal of the direct purchasers case went to the Second Circuit over the objection of defendants, as the court ruled it did not necessarily raise patent law issues. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, Nos. 05-2851 & 05-2852 (2d. Cir. Nov. 7, 2007) (order denying motion to transfer direct purchaser claims because they relied partially on theories involving no substantial question of patent law). The Second Circuit, however, recently requested briefing on whether it should transfer the remaining appeals to the Federal Circuit. *See Cipro*, Nos. 05-2851 & 05-2852, Apr. 29, 2009 Docket Entry (letter to DOJ regarding jurisdictional question).

C. Measuring The Settlement Against The Parties' Subjective Assessment Of The Merits Is Amorphous And Unworkable

The Direct Purchaser Complaints also include allegations concerning Cephalon's own subjective expectations about the outcome of the suit, *see* AC ¶¶ 4, 6, 51. These allegations signal that the Direct Purchasers may advance, as yet another alternative, a standard based on the parties' *subjective* assessment of the patent case. The DOJ recently advocated this approach in a brief to the Second Circuit in *Cipro*. *See* DOJ *Cipro* Br. The DOJ's recent approach, however, is just as amorphous and unworkable as the objective *ex post* inquiry.[21]

Specifically, the DOJ now proposes that any Hatch-Waxman settlement involving a so-called "reverse payment" to the alleged infringer should be treated as presumptively unlawful, with the burden on the defendants to show that "the agreed upon entry date and other terms of entry reasonably reflected their contemporaneous evaluations of the likelihood that a judgment in the patent litigation would have resulted in generic competition before patent expiration." DOJ *Cipro* Br. at 21-27, 30-31.[22]

This subjective approach naively assumes that each settling party had the same "evaluation" of the likelihood of success, and that those "odds" can readily translate into a corresponding settlement entry date. Yet, as previously noted, patent litigation is inherently uncertain, and there is no reason to presume that branded companies and generics litigants will assess the case in the same way, given their very different risk-reward profiles. *See supra* § III(A) & III(B).

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[21] Previously, the DOJ had advocated an objective *ex post* analysis. *See Cipro*, 544 F.3d at 1337.

[22] Thus, the DOJ's standard, like the FTC's standard, considers "reverse payment" settlements presumptively unlawful, a position the Eleventh Circuit held was unjustified in *Schering-Plough*, 402 F.3d at 1074-75.

The subjective assessment approach also presents troubling evidentiary issues, because generally the most accurate case assessments would be protected by the attorney-client privilege and/or work product doctrine. This places litigants in a Catch-22 situation, where they can either waive privilege to defend a settlement or risk treble damages to preserve the privilege, which could inhibit full and frank communications with counsel or chill settlements.

Finally, even assuming these other problems could be overcome, subjective assessment does not present a workable standard that judges or juries could meaningfully apply, but instead leads to an amorphous and ultimately arbitrary inquiry. It is wholly unclear how a fact-finder meaningfully could determine whether an agreed-upon entry date "reasonably" reflected the parties' contemporaneous expectations about the litigation. In the recent DOJ filing regarding this proposed approach, the DOJ posed no workable solution, inconsistently rejecting the need for mathematical precision regarding expectations, but at the same time insisting that even the parties' common belief that the patent was "very likely" to be upheld would not justify a reverse payment settlement. *Id.* at 31.

IV. POLICY ARGUMENTS AGAINST APPLICATION OF THE PREVAILING STANDARD ARE UNAVAILING

Unable to muster legal precedent to support their position, opponents of the scope of the patent test, including Direct Purchasers in prior briefing, have resorted to a disconnected series of ill-conceived policy arguments against "reverse payment" settlements, contending among other things that they are inconsistent with patent law, and the intent, purpose, and/or language of Hatch-Waxman itself. They are wrong.

A. The Prevailing Standard Acknowledges, And Is Premised Upon, The "Probabilistic" Nature Of Patents

Direct Purchasers have argued that patents do not confer an absolute right to exclude but are only "probabilistic," – *i.e.*, not certain to be held valid. According to the argument, the scope

of the patent test wrongly allows patentees to eliminate that uncertainty by settlement, and fails to account for the possibility that the patent would not be upheld. *See* King Drug Status Report at 2 ("Exclusion payments provide something no patent can – guaranteed protection from competition…."). Direct Purchasers miss the point. Courts articulating the scope of the patent test expressly have recognized that patent litigation is uncertain. *See, e.g.*, *Valley Drug*, 344 F.3d at 1308 (characterizing patent litigation as "complex" and "uncertain"); *Asahi Glass*, 289 F. Supp. 2d at 993 ("No one can be *certain* that he will prevail in a patent suit."). Indeed, that very uncertainty, and the undesirability of chilling patent settlements through *ex post* relitigation of the merits of settled cases, is one of the crucial factors underlying the standard. *Valley Drug*, 344 F.3d at 1308. And while it is of course a truism that "reverse payment" settlements hypothetically eliminate the benefit of challenges that (assuming one could forecast) would have been successful, that proves too much because the same is true of "cashless" settlements. Moreover, it is also true that "reverse payment" settlements can be highly pro-competitive measured against a hypothetical outcome where the patentee would have prevailed. *See Schering-Plough*, 402 F.3d at 1074 ("[A]lthough ESI and Upsher obtained less than what they would have received from successfully defending the lawsuits (the ability to immediately market their generics), they gained more than if they had lost."); *Asahi Glass*, 289 F. Supp. 2d at 994 (to same effect).

B. The "Scope Of The Patent" Test Is Consistent With The Intent, Purpose, And Language Of The Hatch-Waxman Act

In prior briefing, Direct Purchasers argued that the scope of the patent test is misguided because "reverse payment" settlements are somehow inconsistent with the intent, purpose, and language of Hatch-Waxman. First, Direct Purchasers have argued that "delay" of generic entry is inconsistent with the Hatch-Waxman goal of fostering generic entry. But as noted above, the

assumption that such settlements always involve "delay" myopically assumes that generic challengers always win patent litigation; compared with a verdict in favor of the patentee, settlements can and do result in *earlier* generic entry to the market (as is the case here). When entry under settlements is measured against the appropriate benchmark of the existing patent term – as in the prevailing scope of the patent test – allegations of "delay" disintegrate.

Moreover, fostering early generic entry was only *one* of the two competing goals in enacting Hatch Waxman. *See Mead Johnson*, 838 F.2d at 1333. Congress also had in mind the equally important objective of protecting pharmaceutical patents, in order to "induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products." *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000). Clearly, there is a tension between these goals. *Id.* (incentivizing innovators and generics are "conflicting policy objectives"). In balancing that tension, Congress made no special rules restricting settlements. Indeed, the statute as enacted in 1984 made no mention at all of settlements, even though Congress must have been aware that the vast majority of patent cases result in settlements.

Even after direct attention was paid to the issue of so-called "reverse payment" settlements during consideration of the 2003 amendments to Hatch-Waxman, the amendments then adopted did not place any substantive conditions on settlements, requiring only that they be filed with the FTC and DOJ. 21 U.S.C. § 355(j)(5)(D)(i)(V). Given that Congress could have set out specific limitations on Hatch Waxman settlements had it so wished, its silence can fairly be construed as deferring to the courts to analyze the propriety of "reverse payment" settlements under standard antitrust, patent, and settlement principles. *See Clackamas Gastroenterology Assocs., P.C. v. Wells,* 538 U.S. 440, 447 (2003) (congressional silence often reflects an expectation that courts will fill gaps).

There is simply no basis to conclude, then, that "reverse payments" are antithetical to the goals of Hatch-Waxman. *See Cipro*, 544 F.3d at 1337 ("[T]he district court correctly concluded that there is no legal basis for restricting the right of a patentee to choose its preferred means of enforcement and no support for the notion that the Hatch-Waxman Act was intended to thwart settlements."). While the FTC continues to lobby Congress to *amend* the law to restrict "reverse payment" settlements, *see, e.g.,* Statement of the FTC Before the Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce, United States House of Representatives, *available* http://www.ftc.gov/os/2009/06/ P859910payfordelay.pdf, such efforts underscore that under the law applicable to this case such settlements are perfectly lawful.

Finally, Direct Purchasers also have argued that Hatch-Waxman's default 30-month litigation stay, *see* 21 U.S.C. § 355(j)(5)(B)(iii), somehow implies that Congress opposed any compromise resulting in later generic entry (even if substantially before patent expiration). This is a *non sequitur*. Congress included an automatic stay of generic entry in the statute because it envisioned a carefully balanced regime under which generics could test patents, and patentees could secure determinations of their rights, without being forced to seek preliminary injunctions. Thirty months was an estimate of the time required to adjudicate (or resolve) Hatch Waxman patent infringement disputes. *See Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003) ("The purpose of the 30-month stay is to allow time for patent infringement litigation"). There is no reasonable basis for any inference that Congress broadly intended this 30-month period as some deadline by which generic entry invariably would occur.

V. DIRECT PURCHASERS LACK STANDING TO ASSERT THE SHERMAN ACT CLAIMS

Direct Purchasers' antitrust claims also should be dismissed for the independent reason

that the Direct Purchasers have failed to plead standing to challenge the Provigil® Settlements. *See* 15 U.S.C. §15 (2000) (conferring a private right of action for damages on those injured "by reason of" an antitrust violation). While they allege that "but for" the settlements they would have paid less for modafinil, AC ¶ 8, they are engaging in impermissible speculation about what would have happened had the Provigil® patent litigation continued. *See*, *e.g.*, *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 127-28 (1969) (future damages not recoverable if the fact of their occurrence is speculative); *Associated Gen. Contractors of Cal. v. Cal. State Council of Carpenters*, 459 U.S. 519, 542 (1983) (no standing where injury claim "rests at bottom on some abstract conception or speculative measure of harm") (internal quotation marks omitted); *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 267 (3d Cir. 1998) (plaintiffs "cannot foist their version of what might have been on the court"); *Pitchford v. PEPI, Inc.*, 531 F.2d 92, 105 (3d Cir. 1975) ("It is not sufficient to show fact of damage by mere speculation or guesswork").

In particular, Direct Purchasers allege that but for the Provigil® Settlements the Generics "likely would have prevailed in the patent suits brought against them by Cephalon, and/or" the Generics "would have launched their generic product[at risk] as early as 2006." AC ¶ 7.[23] Both theories are too speculative to confer standing.

The assertion that generics would have entered the market because Cephalon would have lost the underlying patent litigation is entirely speculative and similar allegations have been rejected by the courts as insufficient to confer standing. *See Cipro,* 261 F. Supp. 2d at 200-02

[23] Under Hatch-Waxman, once a Paragraph IV litigation stay and any other FDA exclusivities expire, the FDA may grant final approval to a first ANDA filer while the patent litigation is still pending. That approval, however, only satisfies the food and drug laws, without altering the patent laws. As a result, the general applicant can enter the market "at risk," meaning that it would be subject to liability under the patent laws and damages based on the patentee's lost profits, potentially trebled, if the generic applicant markets its product but is later found to infringe the patent. *See* 35 U.S.C. § 284 (2000).

(rejecting theory of injury based on litigation outcome as too speculative to confer standing), *citing Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990) (alleged injury depending on a specific outcome of a lawsuit unduly speculative); *see also Bristol-Myers Squibb Co. v. Copley Pharms., Inc.*, 144 F. Supp. 2d 21, 23 (D. Mass. 2000) (second-filer's argument that innovator might invalidate first-filer's ANDA and thereby remove 180-day exclusivity obstacle to entry too speculative); *Lincoln House, Inc. v. Dupre*, 903 F.2d 845, 847 (1st Cir. 1990) (allegation of RICO injury contingent on outcome of separate litigation purely speculative).[24] Not only is the allegation about hypothetical litigation outcome inherently speculative, but any attempted proof necessarily would require *ex post* reassessment of the merits of the patent litigation. Courts articulating the scope of the patent test have rejected such *ex post* assessment because it would be unduly burdensome and would chill settlements. *See supra* § I(A).

As to the theory that *but for* the Provigil® Settlements there would have been "at risk" market entry by the Generics, antitrust plaintiffs cannot pursue claims premised on the hypothetical occurrence of conduct that itself would have been unlawful (*i.e.*, infringing entry) – particularly where, absent success on the merits, any such entry would have been short-lived. Courts have declined to base antitrust liability on unlawful conduct. *See Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358, 362, 364 (7th Cir. 1907) ("[T]rue test" of Sherman Act violation is "whether the people … are deprived of something to which they have a right. … [T]he public was not entitled to profit by competition among infringers."); *see also In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 791-92 (8th Cir. 2006) (loss of consumer benefit

[24] Direct Purchasers attempt to shore up their position by parroting allegations from the defense pleadings and summary judgment briefs in the patent case (AC ¶¶ 73-82), and by conclusory assertions such as that "[d]uring discovery, the Generic Defendants uncovered facts supporting a host of defenses," *Id.* ¶ 72. But these allegations do not render Direct Purchasers' claim any less speculative, because patent litigation is inherently uncertain and its outcome unpredictable. *Valley Drug*, 344 F.3d at 1308.

from unlawful market entry not actionable under antitrust laws); *Access Telecom, Inc. v. MCI Telecomms. Corp.*, 197 F.3d 694, 712-13 (5th Cir. 1999) ("If there is no legal U.S. export market to Mexico and the only U.S. export market affected is the Mexican market, then there is no antitrust injury"). Thus, any claim that the Settlements prevented "at risk" entry necessarily requires demonstration that such entry would have been upheld as legal after full adjudication – which, as set out above – is inherently speculative.

Moreover, even if "at risk" entry alone could be sufficient to establish standing, the Direct Purchaser Complaints must include sufficient factual allegations "plausibly suggesting" that such entry would have occurred. *See Twombly*, 550 U.S. at 557; *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1951 (2009). Without such allegations, "bare assertions … [are] not entitled to be presumed true" for purposes of a Rule 12(b) motion. *Iqbal*, 129 S. Ct. at 1951. Direct Purchasers allege that the Generics "prepared internal projections" for a mid-2006 launch and that Ranbaxy ambiguously stated that it intended to enter the market upon receiving FDA approval, and that Barr ordered supply of modafinil in late 2005. AC ¶¶ 100-101.

But these allegations do not plausibly suggest that generic entry "at risk" was imminent; rather, they could simply reflect the Generics' and third-party preparation for the possibility that they might prevail on their then-pending summary judgment motions. AC ¶¶ 80-82.[25] Therefore, they do not cross the "line between possibility and plausibility," *Iqbal*, 129 S. Ct. at 1949, particularly given that the contextual disincentives in regard to entry "at risk." An "at risk" entrant, if subsequently found liable for infringement, would be liable for damages measured by the patent holder's lost profits (not the generic's actual profits) and, if that infringement were

[25] The only specific reference to at risk entry is to the "projections" of a Wall Street analyst "assum[ing]" at-risk market entry. AC ¶ 100. Such pure speculation does not establish the plausibility required under *Twombly* and *Ashcroft*.

"willful," for treble damages. *See* 35 U.S.C. §284 (2000). Because the profits generics typically earn are less than the profits the innovator company would have earned on the same sales, *see* AC ¶ 46, a finding of infringement in this context can be extremely costly to the generics. *See Cipro*, 261 F. Supp. 2d at 204-05 (rejecting the "at risk" entry theory as too speculative, and observing that because of the prospect of having to pay substantial damages, "a prudent company may well determine that its interests require waiting until a court has decided the patent infringement case before marketing its generic drug").[26]

Finally, the Rite-Aid Plaintiffs add a third theory of injury, that but for the alleged "reverse payments," the parties could have settled on terms providing for generic entry even earlier than the three year advancement included in the Settlements. RAC ¶ 134. This theory – adopted from the FTC's "cashless settlement" paradigm – also is entirely speculative and conclusory, as no facts are pleaded to "plausibly" suggest that the parties would have considered such a settlement. It is therefore precluded by *Twombly*, 550 U.S. at 577, and *Ashcroft*, 129 S. Ct. at 1949.

CONCLUSION

This Court should follow the well-reasoned opinion of the Federal Circuit, as well as the Second and Eleventh Circuits, and hold that Hatch-Waxman patent settlements, even those involving so-called "reverse payments," do not violate the antitrust laws so long as they do not

[26] *Andrx*, 256 F.3d 799, is readily distinguishable. In that case, the settlement agreement at issue was merely an interim agreement that did not resolve the patent litigation and instead involved a payment by the innovator company to the generic solely in exchange for the generic's agreement *not to enter at risk*. Under those circumstances, the court inferred that the generic would have entered at risk but for the payment. *See also Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 758, 767 (D.N.J. 1999) (under same interim settlement, declining to resolve causation issue on pleadings, but noting that it was "*certainly* possible" that generic was refraining from marketing its product during pendency of litigation only because it was being paid $40 million per year not to do so). The rationale of these cases does not apply here, where the settlements resulted in final resolution of the patent claims, and there is no factual basis in the Complaint to infer that the Generic Defendants would have entered at risk had the litigation continued.

restrict competition to any greater extent than the patent itself. The standard is based on sound considerations including fostering innovation and encouraging settlements, and the balance it strikes derives from Supreme Court precedent concerning the intersection of antitrust and patent law. The authority is uniform and the plaintiffs' attempts to manufacture a split of authority lack merit.

Under the scope of the patent standard, the Direct Purchasers' Complaints fail to state a claim, because they allege neither that the Provigil® Settlements restricted the sale of non-infringing products, nor that they prevented Generics entry beyond the patent term. None of the inapposite authority, discredited agency policy views, or inconsistent and unworkable alternative standards offered by opponents of the prevailing standard affords any sound basis to depart from it. Finally, Direct Purchasers lack standing because their allegations that the Generics would have marketed earlier but for the Settlements are too speculative and lack factual foundation. Accordingly, the Direct Purchaser Complaints should be dismissed with prejudice.

Respectfully submitted,

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Dated: August 31, 2009

CERTIFICATE OF SERVICE

I certify that on the date set forth below the foregoing Defendant Cephalon, Inc.'s Motion to Dismiss the Direct Purchasers' First Consolidated Amended Complaint and the Rite Aid Complaint, Memorandum in support, and proposed Order were electronically filed pursuant to the Court's CM/ECF system, and that the documents are available for downloading and viewing from the CM/ECF system. Notice of this filing will be sent to all counsel of record by operation of the CM/ECF system.

s/ Frank R. Emmerich, Jr.
Frank R. Emmerich, Jr.

Date: August 31, 2009